

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

K2M, INC.,)	
)	
Plaintiff,)	
)	
v.)	
)	C.A. No. _____
ORTHOPEDIATRICS CORP. and)	
ORTHOPEDIATRICS US DISTRIBUTION)	
CORP.,)	
)	
Defendants.)	

K2M, INC.'S COMPLAINT FOR PATENT INFRINGEMENT

K2M, Inc. (hereinafter referred to as “K2M”), by and through undersigned counsel, hereby brings this Complaint against Defendants OrthoPediatics Corp. and OrthoPediatics US Distribution Corp. (collectively referred to as “OrthoPediatics” or “Defendants”) and alleges as follows:

NATURE OF THE CASE

1. This is a civil action for patent infringement based on Defendants’ continued infringement of United States Patent No. 9,532,816 (“the ’816 patent”), entitled “Rod Reduction Device and Method of Use.”

THE PARTIES

2. K2M is a corporation organized and existing under the laws of the State of Virginia, having a principal place of business at 600 Hope Parkway SE, Leesburg, VA 20175.

3. Upon information and belief, Defendant OrthoPediatics Corp. is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business located at 2850 Frontier Drive, Warsaw, IN 46582.

4. Upon information and belief, Defendant OrthoPediatrics US Distribution Corp. is a wholly-owned subsidiary of OrthoPediatrics Corp. and is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business located at 2850 Frontier Drive, Warsaw, IN 46582.

JURISDICTION AND VENUE

5. This action for infringement arises under the patent laws of the United States, including 35 U.S.C. §§ 271, 281 and 283-85, *et seq.*

6. This Court has jurisdiction over the subject matter of this action on at least the following grounds:

a. 28 U.S.C. § 1331, this being a civil action arising under the laws of the United States; and

b. 28 U.S.C. § 1338(a), this being a civil action arising under an Act of Congress relating to patent rights.

7. This Court has personal jurisdiction over Defendants because they are incorporated in Delaware, and because, *inter alia*, upon information and belief, Defendants have conducted, and at the time of the filing of this Complaint are conducting, business in Delaware and otherwise have committed acts in Delaware that are the subjects of and/or related to the claims set forth herein.

8. Venue is proper in this Court under the provisions of 28 U.S.C. §§ 1391 and 1400(b).

BACKGROUND

9. K2M was founded in 2004 in Leesburg, Virginia, by industry veterans Eric Major and John P. Kostuik, MD, a former chief of spine surgery at Johns Hopkins School of Medicine and a founding member of the North American Spine Society.

10. From its inception, K2M set out to design, develop and commercialize products for use by spine surgeons in surgery to treat the most complex spinal pathologies, including spinal deformities. Such complex spine surgeries involve derotating and fixing the spine in a straightened position with screws placed into vertebral bodies secured to rods extending along the spine. The task of correcting the position of the spine, seating the rods into the screws and locking the screws to the rods is quite difficult.

11. As part of K2M's effort to improve on the products available to spine surgeons and the surgical techniques for treating scoliosis, K2M developed a unique rod reducer, marketed under the name Cricket[®], and a technique of use that helps surgeons perform complex spine surgeries. For the first time, surgeons attached a Cricket[®] rod reducer to each pedicle screw so that the surgeon could adjust each Cricket[®] independently of the others and gradually approximate the rod to the series of screws. This was a novel approach made possible by the Cricket[®].

12. K2M is a global innovation leader in spinal technologies, reflected by over 350 issued and pending patents worldwide, including over 170 patents issued by the United States Patent and Trademark Office ("USPTO").

13. On June 30, 2015, K2M filed U.S. Patent Application No. 14/609,868 ("the '868 application"), entitled "Rod Reduction Device and Method of Use." The '868

application claims priority to U.S. Patent Application No. 11/777,730, filed on Jul. 13, 2007, now U.S. Patent No. 8,961,523, and lists Michael Barrus and Scott A. Jones as inventors.

14. On October 31, 2016, the USPTO issued a Notice of Allowance with respect to the '868 application, indicating that all of the Examiner's rejections were overcome. On November 28, 2016, the USPTO received the issue fee for the '868 application. On December 14, 2016, the USPTO issued a notification that the '868 application would issue as U.S. Patent No. 9,532,816.

15. On January 3, 2017, the '816 patent was duly and legally issued by the USPTO. A true and correct copy of the '816 patent is attached hereto as Exhibit A and made a part hereof.

16. K2M is the owner, by assignment, of all right, title, and interest in the '816 patent, including the right to bring damages for past infringement. Accordingly, K2M has the right to bring and maintain the present action.

17. On information and belief, OrthoPediatrics was founded in 2006.

18. On information and belief, OrthoPediatrics introduced its RESPONSE spine system in 2015, which is marketed as treating spinal deformity.

19. On information and belief, the RESPONSE spine system includes the JIMINY rod reducer instrument, and is promoted as allowing "simple" rod reduction by virtue of the JIMINY rod reducer instrument.

CLAIMS FOR PATENT INFRINGEMENT

20. Upon information and belief, Defendants are in the business of making, using, commercializing, and/or importing rod reducing devices as described in the '816 patent.

21. In particular, upon information and belief, Defendants manufacture, use, import, and commercialize products covered by one or more claims of the '816 patent, including without limitation, rod reducing devices marketed as the JIMINY rod reducer instrument and/or identified by Defendants with the following model number: 01-1003-5000 (collectively, "the Infringing Products").

22. For example, Defendants infringe claim 16 of the '816 patent, which provides as follows:

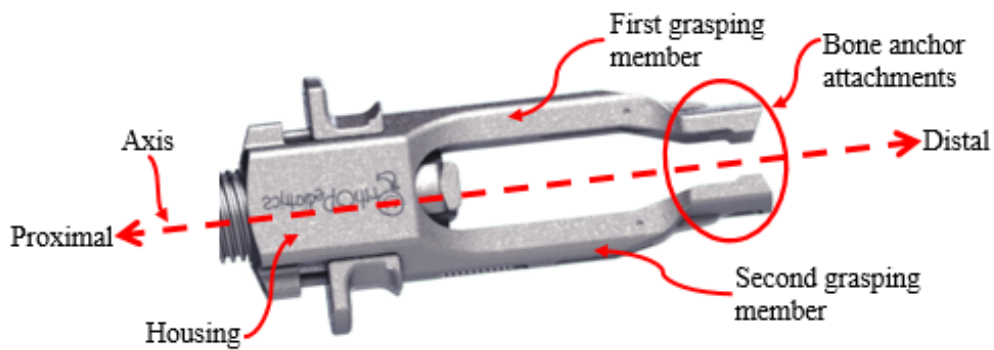
16. A rod reducing device comprising:

a housing defining a longitudinal axis, the housing including first and second grasping members configured to grasp a portion of a bone anchor therebetween, the first and second grasping members defining a plane;

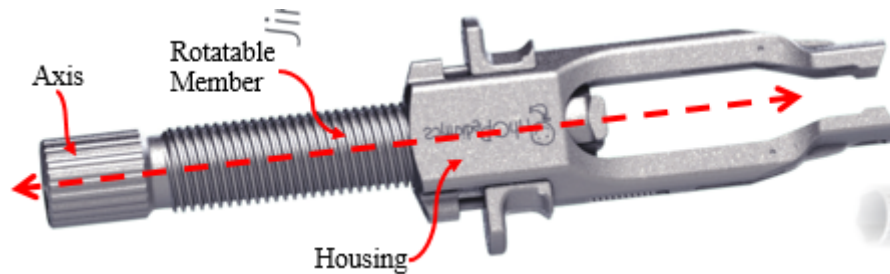
a rotatable member extending through the housing along the longitudinal axis; and

a rod contact member positioned at a distal end of the rotatable member, the rod contact member translatable along the longitudinal axis in response to rotation of the rotatable member about the longitudinal axis, wherein the rod contact member and the rotatable member are translatable within the plane defined by the first and second grasping members.

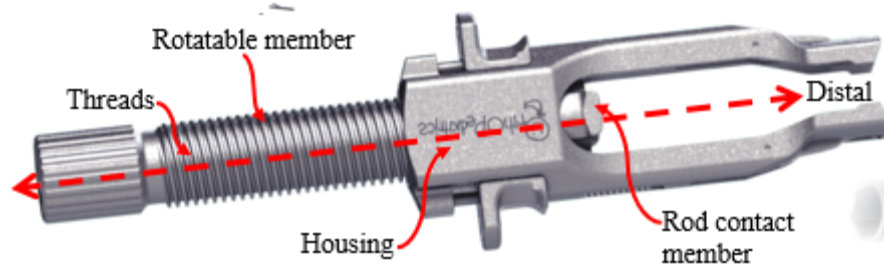
23. Upon information and belief, the JIMINY rod reducer instrument includes a housing defining a longitudinal axis, the housing including first and second grasping members configured to grasp a portion of a bone anchor therebetween, the first and second grasping members defining a plane.



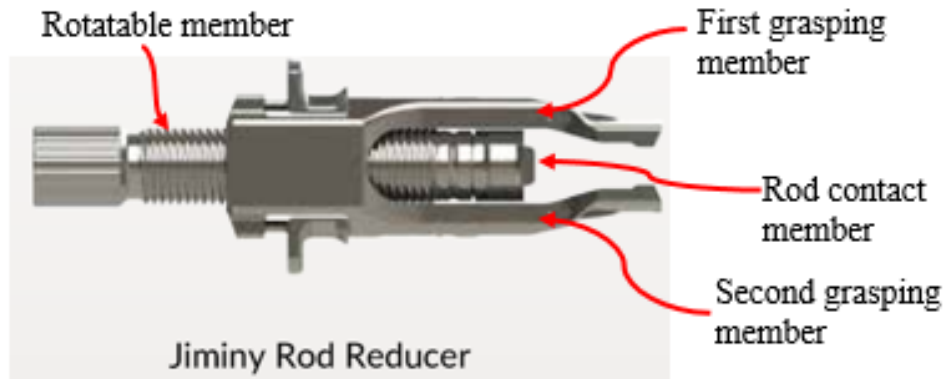
24. Upon information and belief, the JIMINY rod reducer instrument includes a rotatable member extending through the housing along the longitudinal axis.



25. Upon information and belief, the JIMINY rod reducer instrument includes a rod contact member positioned at a distal end of the rotatable member, the rod contact member translatable along the longitudinal axis in response to rotation of the rotatable member about the longitudinal axis.



26. Upon information and belief, the JIMINY rod reducer instrument includes the rod contact member and the rotatable member being translatable within the plane defined by the first and second grasping members.



27. Accordingly, upon information and belief, Defendants are infringing and will continue to infringe, directly and/or indirectly, one or more claims of the '816 patent, either literally or under the doctrine of equivalents, by making, importing, and/or commercializing in the United States products falling within the scope of one or more claims of the '816 patent, including without limitation the Infringing Products, during the legal term of the '816 patent.

28. K2M is being irreparably injured by Defendants' infringement of the '816 Patent and will continue to suffer irreparable injury as long as Defendants' infringement continues. Upon information and belief, Defendants' infringing activities will continue unless enjoined by this Court pursuant to 35 U.S.C. § 283.

29. K2M is suffering and will continue to suffer monetary damages from Defendants' unauthorized infringement that are compensable under 35 U.S.C. § 284 in an amount to be determined at trial.

PRAYER

WHEREFORE, K2M respectfully requests that the Court find in its favor and against Defendants and the Court enter judgment or an order granting K2M the following relief:

- a. That one or more claims of United States Patent No. 9,532,816 are infringed, either literally and/or under the doctrine of equivalents;
- b. That Defendants account for and pay to K2M damages caused by Defendants' infringing activities complained of herein;
- c. That K2M be granted pre-judgment and post-judgment interest at the maximum rate allowable by law on the damages caused by reason of Defendants' infringing activities complained of herein;
- d. That K2M be awarded its costs and reasonable attorney's fees and expenses;
- e. That Defendants be permanently enjoined from any conduct or activity that infringes United States Patent No. 9,532,816; and
- f. That K2M be granted such other and further relief, both legal and equitable, as the Court may deem is just and proper under the circumstances.

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